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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,093	12/17/2003	Richard E. Stein	279.B31US2	3171

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/749,093

Applicant(s)

STEIN ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 6) <input type="checkbox"/> Other: _____ |
| Paper No(s)/Mail Date _____ | |

DETAILED ACTION

The finality of the last office action is withdrawn in view of the newly discovered reference(s). Rejections based on the newly cited reference(s) follow.

Claim Objections

Claim 10 is objected to because of the following informalities: "a fourth...icon" should be "wherein one of the plurality of..." since three other icons have not been previously recited. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-15, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGroot (5987356). DeGroot shows a patient activator in figure 3, with patient query and delivery button, 102, audible generator, 112, and front indicator LEDs, 116. When the patient depresses button 102, the IMD is queried, and returns an indicator/status of the heart rhythm, such as therapy is warranted (AF, AT) or no therapy is warranted, using LEDs and/or audible generator (e.g. as discussed in columns 35-37). It is noted that the patient activator is meant to be carried by the patient and therefore meets the functional use of handheld and that an indication that therapy is warranted is an indication to contact a physician and also indicates information related to a condition of the implanted device in that it has or has not detected arrhythmia and is ready to deliver therapy (in the alternative, see below). In addition, DeGroot

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specifically states that the LEDs and/or audible indications presented on the activator can be changed using similar signals that allow a patient to distinguish between conditions (column 36, lines 63-67) providing a clear indication and motivation that the indicators can be modified. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the status indication system and method as taught by DeGroot, with the use of deadfront status indicator lamps/icons being illuminate by LEDs or different colored LEDS and using natural language messages to communicate the status information since it was known in the art that status indication systems and methods use deadfront status indicator lamps/icons being illuminate by LEDs or different colored LEDS and using natural language messages to communicate the status information to allow the operator to use their visual sense to determine the status of the device which can aid in noisy environments, to allow the device to clearly indicate the status to allow the operator to easily distinguish between different conditions, and to provide natural voice/language messages so the operator does not get confused between different tones and does not have to remember what different tones mean.

In the alternative, for the handheld device, the indication for contacting a physician, and receiving information about the condition of the IMD, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the patient query and status indication system and method as taught by DeGroot, with the system being handheld, having an indicator for contacting a physician, and to receive information related to a condition of the IMD since it was known in the art that patient query and status indication systems and methods use devices that are handheld so the device can be easily carried and used by the patient, to use an indicator for contacting a physician to allow the patient to know when to seek help, and to

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receive information related to a condition of the IMD to allow the physician to determine whether the IMD needs to be replaced or reprogrammed.

Claims 1-4, 7-16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musley et al (2004/0210256). Musley shows a patient activator in figure 1, with patient query button, "?", and a delivery button, "Z", and front indicator LEDs, 62-68. When the patient depresses button "?", the IMD is queried, and returns an indicator/status of the heart rhythm, such as AF present, call physician, or no AF present, using LEDs (e.g. as discussed in paragraph 40). It is noted that the patient activator is meant to be carried by the patient and therefore meets the functional use of handheld and would also contain a self contained power supply to activate the LEDs, and the LEDs also indicate information related to a condition of the implanted device in that it has or has not detected arrhythmia and is ready to deliver therapy (in the alternative, see below). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the status indication system and method as taught by Musley, with the use of deadfront status indicator lamps/icons being illuminate by LEDs or different colored LEDs and using natural language messages to communicate the status information since it was known in the art that status indication systems and methods use deadfront status indicator lamps/icons being illuminate by LEDs or different colored LEDs and using natural language messages to communicate the status information to allow the operator to use their visual sense to determine the status of the device which can aid in noisy environments, to allow the device to clearly indicate the status to allow the operator to easily distinguish between different conditions, and to provide natural voice/language messages so the operator does not get confused between different tones and does not have to remember what different tones mean.

In the alternative, for the handheld device, the self contained power supply, and the information related to a condition of the IMD, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the patient query and status indication system and method as taught by Musley, with the system being handheld, having a self contained power supply, and receiving information related to a condition of the IMD since it was known in the art that patient query and status indication systems and methods use devices that are handheld so the device can be easily carried and used by the patient, to use a self contained power supply to allow the patient to travel freely and untethered to an electrical socket, and to receive information related to a condition of the IMD to allow the physician to determine whether the IMD needs to be replaced or reprogrammed.

Claims 5, 6, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeGroot or Musley (for claims 5, 6, and 17) as applied to the claims above.

DeGroot or Musley disclose the claimed invention except for the different patient rhythms and indications, such as a fast rhythm for 48 hours and the simultaneous use of two indicators of four and no other visual or audible indicators (claims 5, 6, 17), and the use of two separate buttons to query the device and to apply the shock (claim 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patient query and status indication system and method as taught by DeGroot or Musley, the different patient rhythms and indications, such as a fast rhythm for 48 hours and the simultaneous use of two indicators of four and no other visual or audible indicators and the use of two separate buttons to query the device and to apply the shock since it was known in the art that patient query and status indications systems and methods use different patient rhythms and

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indications, such as a fast rhythm for 48 hours and the simultaneous use of two indicators of four and no other visual or audible indicators to allow the physician to dictate what information should be displayed to the patient based on the patients particular condition and the use of two separate buttons to query the device and to apply the shock to prevent the operator from getting confused on what button or button sequence is necessary to query and/or deliver the shock.

Conclusion

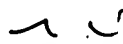
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hamilton et al and Nelms et al are two examples of many showing medical status devices that use backlit icons, i.e. using LEDs to light the icons, and provides natural language voice messages to convey information. Adams and Adams et al are two examples of many showing the use of handheld interrogators and providing indications of when to contact a physician. Tacker et al and Stanton et al are two examples of many showing the indication of information related to the condition of an IMD. Nappholz et al is one example of many showing the use of different rhythms and indications that can be provided to the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

4/25/7

GRE
March 23, 2006